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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Charles S. Neer

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EXAMINER

DOUKAS, MARIA E

ART UNIT

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4166

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/749,894	Applicant(s) NEER, CHARLES S.	
	Examiner MARIA E. DOUKAS	Art Unit 4166	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/2/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/8/04, 5/20/05, 11/2/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-9 and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,034,004 to Crankshaw (Crankshaw).

Crankshaw teaches:

In Reference to Claim 1

Within a contrast media injector system, a method for modifying syringe constants, said method comprising the steps of:

displaying an interface (LCD display panel 13) that permits a service technician to configure one or more service-level aspects of the injector system (col. 8, lines 25-65; col. 9, lines 5-40);

providing within the interface a data collection routine that prompts for the syringe constants (the operator is advised to load a syringe to obtain stroke length: col. 7, lines 47-62; as well as requested to input the syringe volume: col. 8, lines 4-6);

in response to said prompts, receiving input related to the syringe constants (col. 7, lines 47-62; col. 8, lines 4-6; col. 11, lines 6-7); and

updating a syringe definition according to the received input (col. 7, lines 49-50, whereby the loading of the non-standard syringe requires programming of the controller in order to update the syringe data it is using for the infusion profile).

In Reference to Claim 2

The method according to claim 1 (see rejection of claim 1 above), further comprising the steps of:

storing the syringe definition in a non-volatile memory (Figure 2 EEPROM 23) that is part of the injector system (col. 8, lines 13-15).

In Reference to Claim 3

The method according to claim 1 (see rejection of claim 1 above), wherein the syringe constants comprise one or more of a syringe diameter; a syringe stroke length, and a syringe volume (col. 7, lines 47-62; col. 8, lines 4-6).

In Reference to Claim 4

The method according to claim 3 (see rejection of claim 3 above), further comprising the steps of:

requesting data related to two of the syringe constants (col. 7, lines 47-62 requests the user to load an empty syringe to determine stroke length; col. 8, lines 4-6 requests the user to input the syringe volume); and calculating the third syringe constant (col. 8, lines 6-9, whereby the syringe

cross-sectional area is calculated by dividing the syringe volume by the syringe stroke length, and from this syringe diameter can be calculated using the area equation for a cylinder).

In Reference to Claim 5

The method according to claim 1 (see rejection of claim 1 above), further comprising the step of:

modifying one or more operational routines of the injector system affected by the step of updating the syringe definition (col. 8, lines 9-11, whereby the infusion profile will vary depending on the programming of the syringe data).

In Reference to Claim 6

The method according to claim 1 (see rejection of claim 1 above), further comprising the step of:

modifying one or more parameters stored by the injector system which are affected by the step of updating the syringe definition (col. 8, lines 4-9; col. 11, lines 9-18 as the parameter modified is the delivery factor).

In Reference to Claim 7

The method according to claim 1 (see rejection of claim 1 above), further comprising the step of:

associating a label with the syringe information based on the received input (col. 5, lines 35-38 shows that the calibrations loaded in the EEPROM 23 are labeled by syringe volume; col. 8, lines 12-15 indicates that the syringe data that was entered will be stored into the look-up table to replace an existing calibration, and this will therefore be labeled to distinguish it from the other three calibrations stored).

In Reference to Claim 8

The method according to claim 1 (see rejection of claim 1 above), wherein the step of updating includes one of the steps of a) modifying an existing syringe definition or b) creating a new syringe definition (col. 8, lines 14-15, wherein a new syringe definition is created in order to be stored as one of the four calibrations within the look-up table).

In Reference to Claim 9

The method according to claim 2 (see rejection of claim 2 above), further comprising the step of:

deleting another syringe definition from the non-volatile memory before storing the syringe definition (col. 8, lines 13-15).

In Reference to Claim 12

A contrast media injector system (col. 10, lines 31-32, lines 36-37, whereby it states the pump can be used to deliver other fluids besides drugs) comprising:

a processor (Figure 2, central microprocessor 20);

a non-volatile storage coupled with the processor (EPROM 21 and EEPROM 23);
an application stored within said non-volatile storage configured to execute on
said processor (col. 4, lines 49-51), said application including:

an interface (LCD display panel 13) for configuring the injector system;
an input routine configured to receive data related to syringe constants
(col. 7, lines 47-62; col. 8, lines 4-6; col. 11, lines 6-7); and

an updating routine configured to generate a syringe definition based on
the data (col. 7, lines 49-50, whereby the loading of the non-standard syringe
requires programming of the controller in order to update the syringe data it is
using for the infusion profile).

In Reference to Claim 13

The system according to claim 12 (see rejection of claim 12 above), wherein the input
routine is further configured to prompt a technician for a portion of the syringe constants
(col. 7, lines 47-62 prompts the technician to load the syringe to determine stroke
length; col. 8, lines 4-6); to determine an omitted syringe constant; and to calculate the
omitted syringe constant (col. 8, lines 6-9, whereby the delivery factor is calculated from
the syringe stroke length and syringe volume).

In Reference to Claim 14

The system according to claim 12 (see rejection of claim 12 above), wherein the syringe
definition is stored in the non-volatile storage (col. 8, lines 13-15).

In Reference to Claim 15

The system according to claim 12 (see rejection of claim 12 above), further comprising:

an operational application stored in the non-volatile storage (col. 4, lines 39-40), said operational application includes one or more control routines to operate an injector of said injector system (col. 4, lines 39-42), wherein the control routines use the syringe definition to operate the injector (col. 8, lines 9-11; col. 11, lines 9-14, as the programmed syringe data is used to perform the infusion profile).

In Reference to Claim 16

A method for updating an injector system comprising the steps of:

entering a service mode of the injector system (col. 8, lines 25-65; col. 9, lines 5-40, whereby the user enters the service mode to program the pump to perform the desired infusion);

inputting one or more syringe constants (the operator is advised to load a syringe to obtain stroke length: col. 7, lines 47-62; as well as requested to input the syringe volume: col. 8, lines 4-6)

based on the one or more syringe constants, calculating an additional syringe constant (col. 8, lines 6-9, whereby the syringe cross-sectional area is calculated by dividing the syringe volume by the syringe stroke length, and from this syringe diameter can be calculated using the area equation for a cylinder).; and

storing a syringe definition in the injector system based on the one or more syringe constants and the calculated syringe constant (col. 8, lines 13-15).

3. Claims 1 and 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,741,732 to Crankshaw (Crankshaw').

Crankshaw' teaches:

In Reference to Claim 1

Within a contrast media injector system, a method for modifying syringe constants, said method comprising the steps of:

displaying an interface (LCD display 110) that permits a service technician to configure one or more service-level aspects of the injector system (col. 8, lines 65-66; col. 9, lines 21-28);

providing within the interface a data collection routine that prompts for the syringe constants (col. 11, lines 25-43);

in response to said prompts, receiving input related to the syringe constants (col. 11, lines 25-43); and

updating a syringe definition according to the received input (col. 11, lines 25-43 as the inputted data is used to calibrate the system so that the plunger movement is properly adjusted based on the syringe definition).

In Reference to Claim 10

The method according to claim 1 (see rejection of claim 1 above), further comprising the steps of:

 exiting the interface (col. 11, lines 54-67, whereby the LCD display 110 is exited and patient data is entered into LCD display 111);

 displaying an operational interface whereby an operational routine is executed (LCD display 109, 112; col. 8, lines 58-62; col. 12, lines 10-13, lines 17-19, whereby the run button is pressed to begin drug infusion and displays 109 and 112 show accumulated dose of drug administered and elapsed time, respectively).

In Reference to Claim 11

The method according to claim 10 (see rejection of claim 10 above), wherein the operational routine relies on the syringe definition (col. 11, lines 31-39; col. 12, lines 28-32, whereby the syringe inputs determine plunger movement and influence the doses of drug infused).

4. Claims 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,200,289 to Hochman (Hochman).

Hochman teaches:

In Reference to Claim 17

A method for updating an injector system comprising the steps of:

entering a service mode of the injector system (Figure 11, col. 9, lines 21-28, whereby the clinician can setup the drug infusion system by entering data on the syringe, tubing, etc.);

inputting at least three syringe constants (Figure 12A, col. 9, lines 24-40, whereby the different syringes' physical characteristics listed were entered in order to be stored in the database; col. 9, lines 50-53, whereby the syringe cross sectional area can be calculated and entered) ;

and storing a syringe definition in the injector system based on the three syringe constants (Figure 12A, col. 9, lines 24-40, whereby the syringe definition is stored in a database).

In Reference to Claim 18

The method according to claim 17 (see rejection of claim 17 above), wherein the at least three syringe constants comprise a syringe diameter; a syringe stroke length, and a syringe volume (col. 9, line 40 lists the syringe stroke length and syringe volume; col. 9, lines 50-53, whereby the syringe cross sectional area is entered, and therefore provides the syringe diameter based on the equation for cylinder cross sectional area).

In Reference to Claim 19

The method according to claim 17 (see rejection of claim 17 above), further comprising the step of:

updating a software routine within the injector system which relies on the syringe definition (col. 10, lines 17-25, lines 32-34, whereby the syringe definition chosen will influence the infusion profile that is either chosen or calculated).

In Reference to Claim 20

The method according to claim 17 (see rejection of claim 17 above), wherein the one or more syringe constants are selected from the group comprising: syringe diameter, syringe stroke length, and syringe volume (col. 9, line 40, lines 50-53).

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,814,015 (Gargano) and U.S. Patent No. 5,681,285 (Ford) both describe systems that allow the user to specify syringe size and syringe manufacturer.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA E. DOUKAS whose telephone number is (571)270-5901. The examiner can normally be reached on Monday - Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ken Bomberg can be reached on (571)272-4922. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 4124

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MD

/Kenneth Bomberg/

Supervisory Patent Examiner, Art Unit 4124

